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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/589,862

04/30/2007

Suresh Pareek

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01/06/2010

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EXAMINER

TRAN, SUSAN T

ART UNIT

PAPER NUMBER

1615

MAIL DATE

DELIVERY MODE

01/06/2010

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/589,862	Applicant(s) PAREEK ET AL.	
	Examiner S. Tran	Art Unit 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 September 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-18 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Amendment

The amendment filed 09/23/09 is objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: the phrase "about 90%" added to paragraph on page 4, line 7; the phrase "about 40%" added to paragraph page 4, line 21; and the phrase "about 50%" added to paragraph page 4, line 27. The original filed claims do not recite the limitation "about".

Applicant is required to cancel the new matter in the reply to this Office Action.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 9 and 10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 9 is rejected because the phrase "comprising a pigment at least one" is confusing. Did it mean "comprising at least one pigment"?

Claim Rejections - 35 USC § 103

Claims 1-8, 11-15 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Deshpande et al. US 2004/0028737, in view of Mehra et al. US 5,733,575.

Deshpande teaches an enteric coating composition comprising methacrylate copolymer type C, polyethylene glycol 600, titanium dioxide, and talc (examples 1-4 and 8). The amounts of the above components disclosed in the examples fall within the claimed ranges, e.g., about 60% methacrylate copolymer type C, about 6% plasticizer, about 7% opacifier, and about 24% detackifier.

Deshpande does not expressly teach that the coating composition is in powder form.

Mehra teaches a powder coating composition that is non-toxic and edible. The powder coating composition comprising enteric film forming polymer (abstract; and columns 3-4). Thus, it would have been obvious to one of ordinary skill in the art to prepare a coating composition in powder form in view of the teachings of Mehra to obtain the claimed invention. This is because Mehra teaches a dry powder coating that can overcome the disadvantages of the known aqueous coating compositions (column 1), because Mehra teaches a dry powder coating composition that is non-toxic and edible, because Mehra teaches that a dry powder coating composition provides an enteric coating that is less tacky and does not have the odor of ammonium hydroxide, and because Mehra teaches that a dry powder coating composition is known in the art.

Claims 9, 10, 16 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Deshpande et al. US 2004/0028737, in view of Mehra et al. and Kokubo et al. US 4,948,622.

Deshpande is relied upon for the reason stated above. Deshpande does not expressly teach the use of pigment in the coating composition.

Kokubo teaches a coating composition comprising edible dyes, and edible lake pigments (column 3, lines 45-50). Thus, it would have been obvious to one of ordinary skill in the art to modify the coating composition of Deshpande to include the use of edible pigments in view of the teachings of Kokubo to obtain the claimed invention. This is because Kokubo teaches that the presence of pigment in a coating composition is well known in the art.

Response to Arguments

Applicant's arguments filed 09/23/09 have been fully considered but they are not persuasive.

Applicant argues that Deshpande discloses a bilayer enteric coating, of which an inner layer is neutral or near neutral such as pH 7-7.5 and an outer layer is acidic such as pH 2-6 (see abstract). The reference further discloses examples that include a methacrylate copolymer, polyethylene glycol, titanium dioxide, and talc (see examples 1-4 and 8). To adjust the pH of the inner layer of these examples, Deshpande uses 2M ammonia solution, i.e., an alkalinizing agent, which is excluded from claim 1. Thus, the enteric film coating dry powder composition of claim 1 is distinguished from the inner

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layer of Deshpande. In addition, Deshpande fails to disclose the outer layer that includes a methacrylate copolymer of Type C, a plasticizer, a film coating detackifier, and an opacifier and no alkalinizing agent as claim 1 recites. Further, the reference discloses that the outer layer coating is carried out using an aqueous dispersion of the enteric material (see para. [0037]) and that examples 1-4 and 8, which include methacrylate copolymer, polyethylene glycol, titanium dioxide, and talc in the inner layer, contain 3 % w/v castor oil in the outer layer, and thus Deshpande also fails to disclose the outer layer that is a dry power composition as claim 1 recites (see examples 1-4 and 8).

However, in response to applicant's arguments that the coating taught by Deshpande is not a dry powder composition, it is noted that a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. Similar to the teachings of Deshpande, the examples in the present specification disclose that the dry powder composition of the present invention is suspended in aqueous solution to obtain a suitable coating suspension useful for coating solid dosage form.

In response to applicant's argument that Deshpande uses 2M ammonia solution, i.e., an alkalinizing agent, which is excluded from claim 1, it is of note that the 2M ammonia solution is used for the inner coating layer with a neutral pH. The outer coating layer having pH near acidic does not require the use of alkalinizing agent. See

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for example, paragraphs 0060, 0062 and 0068. The claims do not preclude the inner coating layer, nor the castor oil in the outer coating layer.

Accordingly, for at least the above reason, the rejection by Deshpande is maintained.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to S. Tran whose telephone number is (571) 272-0606.

The examiner can normally be reached on M-F 8:30 am to 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert A. Wax can be reached on (571) 272-0623. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/S. Tran/
Primary Examiner, Art Unit 1615

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